



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/595,371

02/16/2007

Duncan Keeble

78104107/N18438

8373

25005

7590

05/15/2008

Intellectual Property Dept.
Dewitt Ross & Stevens SC
2 East Mifflin Street
Suite 600
Madison, WI 53703-2865

EXAMINER

TANNER, JOCELYN C

ART UNIT

PAPER NUMBER

4133

MAIL DATE

DELIVERY MODE

05/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,371	Applicant(s) KEEBLE ET AL.	
	Examiner JOCELIN C. TANNER	Art Unit 4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/13/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is in response to the application filed on February 16, 2007 in which claims 1-26 are presented for examination.

Status of Claims

Claims 1-26 are pending, of which 2 are in independent form. Claims 1, 2, 3, 4, 5, 7, and 8 are rejected under 35 U.S.C. 102(b). Claims 6, 9, 10-13, 15-26 are rejected under 35 U.S.C. 103(a).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 13, 2006 was filed before the mailing date of the patent application on February 16, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tube extending through the segments (claim 20) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

Art Unit: 4133

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 21 is objected to because of the following informalities: claim 21 references "the tube" and should be dependent on claim 20 instead of claim 19 which does not refer to a tube. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 4133

4. Claims 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 19, the recitation "extends through each segment spaced from the segment's outer circumference", renders the claim vague and indefinite since it is unclear which segment is being referenced.

6. Claim 21 recites the limitation "the tube" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is unclear if this claim should be dependent on claim 20.

7. **As best understood, in light of the rejections under 35 U.S.C. 112 second paragraph above, claims 19 and 21 are rejected under 35 U.S.C. 103(a) below.**

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Komachi (US Patent No. 6,408,889).

Regarding independent claim 1, Komachi discloses a bendable tube or "articulated device" (10) for advancing a medical implant along a catheter, the device including a plurality of joint pieces or "segments" (11) arranged one after the other in

line, each segment being rotatably or “hingeably” connected to a single adjacent segment (FIG. 2, element #11) if it is at the end of the line and otherwise to two adjacent segments, whereby a medical implant mounted at one end of the device can be advanced through a catheter by pushing on the other end of the device, the hinged connections allowing the device to follow a curved path through the catheter, characterized in that each segment is detachable from its adjacent segment(s). Please see figures 1 and 2.

Examiner notes that the device of Komachi is capable of having a medical implant mounted thereon to be advanced through a catheter. Regarding the limitation, “whereby a medical implant mounted at one end of the device can be advanced through a catheter by pushing on the other end of the device, the hinged connections allowing the device to follow a curved path through the catheter, characterized in that each segment is detachable from its adjacent segment(s)”, the Examiner notes that the manner or method in which an device is to be utilized is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)).

9. Regarding claim 2, Komachi discloses each joint pieces or “segments” (FIG. 2, element #11) having a protrusion or “male part” (FIG. 2, element #13a) and a through-hole or “female part” (FIG. 2, element #12a), the male part of a segment being able to engage with the female part of an adjacent segment, and the female part being able to engage with the male part of an adjacent segment (column 4, lines 57-68 and column 5,

Art Unit: 4133

lines 1-7) wherein the protrusion engages within the through-hole, thus connecting the two joint pieces.

10. Regarding claim 3, Komachi discloses a protrusion or “male part” having a pair of projections and the through-hole or “female part” having a slot for accepting the projections (column 5, lines 51-55, FIG. 7, element #13a') wherein the joint pieces can be prevented from being disconnected by having protrusions with extended sides engaging within the through-hole or “female part”.

11. Regarding claim 4, Komachi discloses a protrusion or “male part” having a ball and a through-hole or “female part” having a socket (column 5, lines 4-7) wherein the protrusion is radially shaped (i.e. a ball) and the through-hole is hollow for receiving the protrusion.

12. Regarding claim 5, Komachi discloses joint pieces or “segments” (FIG. 2, element#11) that are formed from metal, a material which is sufficiently stiff, and capable of allowing a moment of at least 1 Newton metre to be transmitted through the device (column 4, line 12).

13. Regarding claim 7, Komachi discloses a lumen passing through each joint piece or “segment” along its longitudinal axis, so that the plurality of lumen substantially align

Art Unit: 4133

to allow a guide wire to pass therethrough when the device is in use (FIG. 2) wherein the connected joint pieces or segments form a bendable tube.

14. Regarding claim 8, Komachi discloses a wire insertion hole or "channel" (11a) in the outer wall of each joint piece or "segment" (column 4, lines 21-23) so that the plurality of channels substantially align to allow a control wire or "guide wire" (20) to pass therethrough when the device is in use (FIG.1).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komachi (US Patent No. 6,408,889).

16. Regarding claim 9, Komachi discloses a length of joint pieces or "segments" and the widest diameter of each segment such that the ratio of the length to the widest diameter would fall in the range of 1:1 to 1:5 since it has been held that, where the only difference between the prior art and the claims is the recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than a prior art device, the claimed device is not patentably distinct

from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F. 2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

17. Regarding claim 10, Komachi discloses all of the limitations previously discussed except for a maximum degree of articulation between the longitudinal axis of one segment and the longitudinal axis of an adjacent segment of at least 15.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have chosen a maximum degree of articulation of at least 15 degrees since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

18. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komachi (US Patent No. 6,408,889) in view of Geitz (US Patent No. 6,146,389).

Regarding claims 11 and 12, Komachi discloses all of the limitations previously discussed in claim 1 except for a medical implant mounted on one end of the device.

Geitz teaches a stent deployment device having a stent, a "vascular graft", or a "medical implant" (22) circumferentially compressed over the protective cap (20) at the distal end of a flexible endoscope or "articulated device" (10) (column 3, lines 12-15, line 37 and 44-45). Please see figure 1.

Because Komachi and Geitz teach known elements, i.e. endoscopes, it would have been obvious to one of ordinary skill in the art to have applied the known

technique of attaching an implant to the distal end of the endoscope of Geitz, to the bending tube of Komachi for the predictable result of increasing the flexibility for positioning a stent within a vessel.

19. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komachi (US Patent No. 6,408,889), and Geitz (US Patent No. 6,146,389) as applied to claim 11, and further in view of Solomon et al (US Patent No. 5,749,828).

Regarding claim 13, the combination of Komachi and Geitz discloses all of the limitations of claim 11 except for a delivery catheter.

Solomon et al teach an elastomeric jacket or "delivery catheter" that encases the endoscope when it is inserted into the body cavity to seal the links of the endoscope from the surrounding body tissue (column 4, lines 23-27).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the bending tube device of the combination of Komachi and Geitz, with the elastomeric jacket, as taught by Solomon, to provide easier insertion of the bending tube into body cavities.

20. Regarding claim 15, the combination of Komachi, Geitz and Solomon discloses all of the limitations previously discussed in claim 1 and the following method steps: an implant mounted on one end of the device (column 3, lines 43-45, FIG. 1, Geitz), inserting end of the device into an elastomeric jacket or "catheter" (column 4, lines 23-

26, Solomon), and pushing on the other end of the device when inserting the implant into the body cavity.

The method steps of claim 15 are rendered obvious by the above discussion.

21. Claims 6 and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komachi (US Patent No. 6,408,889) in view of Solomon et al (US Patent No. 5,749,828).

Regarding claim 6, Komachi discloses all of the limitations previously discussed except for explicitly stating the device having 15 segments.

Solomon et al teach varying the number of sleeves or "segments" in a bending neck or "articulated device" depending on the overall desired length of the articulated device for a particular application (FIG. 4A, element#12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected 15 or more segments within the articulated device of Komachi, as taught by Solomon et al, to have the ability to vary the number of segments in order to suit a particular application.

22. Regarding independent claim 16, Komachi discloses a bendable tube or "articulated device" (FIG. 1, element #10) including: multiple joint pieces or "segments" (FIG. 2, element #11) wherein:

(1) each segment pivotally abuts any adjacent segments (column 5, line 16), whereby the line of adjacently arrayed segments may adopt a curved path within the catheter,

Art Unit: 4133

and

(2) the segments are translatable within the passage (column 5, lines 12-14), whereby the segment at one end of the line can:

(i) can have a medical implant situated thereon, and

(ii) can be advanced through at least a major portion of the length of the catheter interior passage to eject the medical implant from a passage exit.

However, Komachi fails to disclose a catheter.

Solomon et al or "Solomon" herein, teaches an elastomeric jacket or "catheter" (column 4, lines 23-27) that provides easier insertion of the bending neck or "articulated device".

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the bendable tube of Komachi with the elastomeric jacket, as taught by Solomon, for the predictable result of smooth insertion of the articulated device into the body cavity.

Examiner notes that the device of combination of Komachi and Solomon is capable of having a medical implant mounted thereon to be advanced through a catheter. Regarding the limitations, "whereby the line of segments may adopt a curved path within the catheter", "whereby the segment at one end of the line can: have a medical implant situated thereon, and be advanced through at least a major portion of the length of the catheter interior passage to eject the medical implant from a passage exit", the Examiner notes that the manner or method in which an device is to be utilized

is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)).

23. Regarding claim 17, the combination of Komachi and Solomon discloses all of the limitations. The Examiner notes Komachi discloses a wire insertion hole or "passage" (FIG. 2, element #11a) defined within each segment, wherein the passages are aligned when the segments are arrayed in a line to define a passage extending axially along the arrayed segments (column 4, lines 22-23).

24. Regarding claim 18, the combination of Komachi and Solomon disclose all of the limitations. Komachi discloses a wire insertion hole or "passage" (FIG. 1, element #11a) on the outer circumference of each joint piece or "segment" (column 4, lines 21-23) wherein the wire insertion hole extends from the inner to outer portion of the segment.

25. Regarding claim 19, the combination of Solomon and Komachi discloses all of the limitations. Komachi discloses a wire insertion hole or "passage" (FIG. 1, element #11a) of each joint piece or "segment" that is spaced from the outer perimeter of the segment.

26. Regarding claim 20, the combination of Solomon and Komachi discloses all of the limitations. Solomon further teaches a tube extending through the segments wherein

multiple connecting links (FIG. 3A, element #2) form a tube within the bending neck (FIG. 4A, element #20).

27. Regarding claim 21, the combination of Solomon and Komachi discloses all of the limitations. Solomon further teaches sleeves (FIG. 4A, element #12) that are positioned over the multiple links or a "tube" and are held in place or "affixed" by tabs ((FIG. 3B, element #4).

28. Regarding claim 22, the combination of Solomon and Komachi discloses all of the limitations. Komachi discloses a joint piece or "segment" (FIG. 1, element#10) that resiliently snap-fit to at least one adjacent segment (FIG. 2) wherein the through-hole or "female part" (FIG. 2C, element #13a) receive the corresponding protrusion or "male part" (column 5, lines 1-6, FIG. 2, element #12a).

29. Regarding claim 23, the combination of Solomon and Komachi discloses all of the limitations. Komachi further discloses each segment bearing one or more protrusions or "projections" (FIG. 2, element #112a), each projection being engaged to an adjacent segment (FIG. 2).

30. Regarding claim 24, the combination of Solomon and Komachi discloses all of the limitations. Komachi further discloses a protrusion or "ball" having a pair of projections extending from the ball and the through-hole or "female part" having a slot

for accepting the projections (column 5, lines 51-55, FIG. 7, element #13a') wherein the joint pieces can be prevented from being disconnected by having protrusions with extended sides engaging within the through-hole or "female part".

31. Regarding claim 25, the combination of Solomon and Komachi discloses all of the limitations. The Examiner notes that Komachi further discloses joint pieces or "segments" (FIG. 2, element#11) having lengths, as measured along the line. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided lengths of segments that were less than or equal to their diameters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

32. Regarding claim 26, the combination of Solomon and Komachi discloses all of the limitations. Komachi discloses diameters of joint pieces or "segments" of 1-2mm (column 4, line 17) which is "approximately" 10mm or less.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Danitz et al (US Patent No. 7,090,637), Heimberger et al (US Patent No. 5,772,578) and Jaffe et al (US Patent No. 6,837,846) are related to articulating mechanisms and applications including manipulation of surgical or

Art Unit: 4133

diagnostic instruments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
Examiner, Art Unit 4133

5/8/2008
/Frantz Coby/
Supervisory Patent Examiner
Art Unit 4133

Application/Control Number: 10/595,371
Art Unit: 4133

Page 16